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EXAMINER	
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1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/645,977	KIEL ET AL.	
	Examiner	Art Unit	
	Leslie A. Royds	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21,31-38,40-48 and 53-64* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21,31-38,40-48 and 53-64* is/are rejected.

7)☒ Claim(s) *53 and 63* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *28 March 2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-21, 31-38, 40-48 and 53-64 are presented for examination.

A request for continued examination under 37 C.F.R. 1.114, including the fee set forth in 37 C.F.R. 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 C.F.R. 1.114, and the fee set forth in 37 C.F.R. 1.17(e) has been timely paid, the finality of the previous Office Action has been withdrawn pursuant to 37 C.F.R. 1.114. Applicant's payment and submission filed March 28, 2007 has been received and entered into the present application. Accordingly, prosecution has been reopened.

Applicant's Information Disclosure Statement (IDS) filed March 28, 2007 has also been received and entered into the present application. As reflected by the attached, completed copy of form PTO/SB/08a (two pages total), the Examiner has considered the cited references.

Acknowledgement is also made of Applicant's change of correspondence address, new legal representation and new assignment of the instant application as noted at page 9 of Applicant's remarks.

Claims 1-21, 31-38, 40-48 and 53-64 are pending and under examination. Claim 39 is cancelled, claims 1, 3, 5, 14-15, 20, 31-32, 34-38, 40-43 and 53 are amended and claims 54-64 are newly added.

Applicant's arguments, filed March 28, 2007, have been fully considered. Rejections not reiterated from previous Office Actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

Objection to the Claims (New Ground of Objection)

Claim 63 is objected to for misspelling the word "hardness" as "harness" at line 3 of the claim.

Claim 53 is objected to for reciting the phrase "combining excipients to said second solution", which is grammatically awkward. A combination step of two components should properly read a

combination "with", not "to". Applicant may wish to consider amending the claim to read ---combining excipients with ~~to~~ said second solution--- for grammatical clarity.

Claim Rejections - 35 USC § 112, First Paragraph, Written Description Requirement

(New Grounds of Rejection)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-21, 31-38, 40-48, 53-56 and 58-59 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant has failed to specifically correlate portions of the specification to the newly added claim limitations, but provides diffuse reference to the specification as a whole and specifically cites page 4, lines 6-10, page 5, line 23-page 8, line 25, page 10, line 19-page 12, line 5, Tables 1-2, page 19, lines 1-10, and original claims 1, 31, 35 39 and 53. The specification and claims as originally filed have each been fully and carefully considered in their entirety, but fail to provide adequate written support for all of the newly added and/or amended claim limitations.

In particular, Applicant has failed to provide adequate written support for the claimed limitations directed to:

(1) dissolving the salt or free base of the active pharmaceutical ingredients in a first solvent to form a first solution at any other conditions other than those that do not cause decomposition of the active pharmaceutical ingredients (claims 1, 31 or 53),

(2) transferring at least a portion of the solution to the dispersion to form tannate salts of the

active pharmaceutical ingredients without isolation or purification to form a second solution, wherein said transferring results in a composition consisting of pyrilamine tannate, phenylephrine tannate and dextromethorphan tannate with reduced variability in active pharmaceutical ingredient content and increased certainty that said active pharmaceutical ingredients are delivered within a therapeutic range (claim 53), and

(3) combining said second solution with said liquid pharmaceutical carrier to result in a composition consisting of pyrilamine tannate, phenylephrine tannate and dextromethorphan tannate with reduced variability in active pharmaceutical ingredient content and increased certainty that said active pharmaceutical ingredients are delivered within a therapeutic range (claim 59).

Regarding (1), the specification and claims as originally filed fail to provide adequate written support to now broaden the claims to encompass the dissolution of the salt or free base of the active pharmaceutical ingredients (APIs) in a first solvent to form a first solution at any other conditions other than those that do not cause decomposition of the active pharmaceutical ingredients. Applicant discloses in both the originally filed specification and claims that this step of dissolution of the salt or free base of the APIs in a first solvent to form a first solution must be performed at conditions that do not cause degradation of the composition and/or the APIs. Please see, e.g., page 6, lines 18-24, page 15, lines 17-21 and originally filed claims 1, 31 and 53. The disclosure of this dissolution step specifically at conditions that do not cause degradation or decomposition of the APIs is not sufficient or adequate written support to now broaden the claims to read upon this dissolution step at any conditions that may or may not cause degradation or decomposition of the composition and/or APIs. Accordingly, the concept of performing the dissolution step at any conditions represents a broadening of the subject matter originally disclosed that does not have adequate written basis in the original specification and claims.

Regarding (2) and (3), the specification and claims as originally filed fail to provide adequate written support to now narrow the claims to those compositions that have reduced variability in active

pharmaceutical ingredient content and increased certainty that said active pharmaceutical ingredients are delivered within a therapeutic range (claims 53 and 59). Applicant relies upon the disclose at page 4, lines 6-10 in support of this limitation, which states, "Therefore, it would be desirable if pharmaceutical compositions containing pyrilamine, phenylephrine, and dextromethorphan tannates could be prepared with reduced variability in active drug content and increased certainty that the active pharmaceutical ingredients are delivered within a therapeutic range." However, it is noted that this disclosure found at page 4, lines 6-10 does not directly refer back to Applicant's claimed inventive composition, but rather refers to a need of compositions already known in the art. In light of such, the fact that Applicant may have expressed the need or desire for a process of making compositions comprising phenylephrine, pyrilamine and dextromethorphan with reduced variability in the active drug content such that one would have "increased certainty" that the active pharmaceutical ingredients were delivered within a therapeutic range does not provide adequate written support to now claim that Applicant's own inventive composition has this same reduced variability and therapeutic dosage amounts. Accordingly, the concept of producing a composition with reduced variability in drug content and a higher degree of probability that the APIs are delivered within a therapeutic range represents a narrowing of the subject matter originally disclosed that does not have adequate written basis in the original specification and claims.

Considering the teachings provided in the specification and claims as originally filed, Applicant has failed to provide the necessary teachings, by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams and formula that fully set forth the claimed invention, in such a way as to reasonably convey to one skilled in the relevant art that Applicant had possession of the concepts of (1) dissolving the salt or free base of the active pharmaceutical ingredients in a first solvent to form a first solution at any other conditions other than those that do not cause decomposition of the active pharmaceutical ingredients (claims 1, 31 or 53), (2) transferring at least a portion of the solution to the dispersion to form tannate salts of the active

pharmaceutical ingredients without isolation or purification to form a second solution, wherein said transferring results in a composition consisting of pyrilamine tannate, phenylephrine tannate and dextromethorphan tannate with reduced variability in active pharmaceutical ingredient content and increased certainty that said active pharmaceutical ingredients are delivered within a therapeutic range (claim 53), and (3) combining said second solution with said liquid pharmaceutical carrier to result in a composition consisting of pyrilamine tannate, phenylephrine tannate and dextromethorphan tannate with reduced variability in active pharmaceutical ingredient content and increased certainty that said active pharmaceutical ingredients are delivered within a therapeutic range (claim 59).

Accordingly, for these reasons, claims 1-21, 31-38, 40-48, 53-56 and 58-59 are properly rejected under 35 U.S.C. 112, first paragraph, for failing to comply with the written description requirement.

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-21, 31-38, 40-48 and 53-59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention, for the reasons of record set forth at pages 10-12 of the previous Office Action dated October 30, 2006, insofar as the rejection was set forth regarding the limitation "without isolation or purification", of which said reasons are herein incorporated by reference.

Newly added claims 54-59 are properly included in this rejection because they are dependent from claim 1 and do not further clarify the intent of the claimed limitation "without isolation or purification".

Applicant traverses the instant rejection, stating that the claims as presently amended clearly set forth that the solutions of the tannate salts are combined without isolation or purification with the liquid pharmaceutical carrier or powder mixture or dispersion and that the rejection should be withdrawn.

Applicant's traversal has been fully and carefully considered, but fails to be persuasive.

It is noted that the claims as presently written still do not clearly set forth that it is the *tannate salts* that are not isolated or purified prior to their combination with the liquid pharmaceutical carrier, powder mixture or dispersion. Though Applicant states at page 12 of the remarks that the intent of the claimed limitation "without isolation or purification" is intended to refer back to the tannate salts of the active pharmaceutical ingredients, the claims do not clearly delineate this fact. For example, claim 1 recites, "combining the second solution, without isolation or purification, with said liquid pharmaceutical carrier". Though the second solution may comprise tannate salts, it is not clear what, in fact, is not further isolated. Are the tannate salts not further isolated or purified prior to combination with the carrier? Are the tannate salts plus the carrier not further isolated or purified after their combination? Accordingly, it remains that the claims do not clearly delineate on the record to which components and/or combination the isolation or purification step actually refers.

For these reasons provided *supra*, and those previously made of record at pages 10-12 of the previous Office Action dated October 30, 2006, rejection of claims 1-21, 31-38, 40-48 and 53-59 is proper and is **maintained**.

Claim Rejections - 35 USC § 112, Second Paragraph (New Grounds of Rejection)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3 and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Present claims 3 and 32 are directed to the salt or free base of the active pharmaceutical ingredients of the claimed composition (i.e., phenylephrine, pyrilamine and dextromethorphan), "wherein the salt or free base of said active pharmaceutical ingredients are selected from the group consisting of maleate, citrate, chloride, bromide, acetate, and sulfate."

In particular, it is noted that the claims fail to clearly delineate how the "free base" form of the claimed active pharmaceutical ingredients of phenylephrine, pyrilamine and dextromethorphan is in the form of a maleate, citrate, chloride, bromide, acetate or sulfate salts. It is understood that the free base form of the active pharmaceutical ingredients would be those that are in basic form, i.e., not conjugated to an acid. Accordingly, it is unclear how the free base forms of the claimed pharmaceutical ingredients can be maleate, citrate, chloride, bromide, acetate or sulfate "free bases". As a result, Applicant has failed to clearly, precisely and/or deliberately set forth the metes and bounds of the subject matter for which he is seeking patent protection.

For these reasons, the claims fail to meet the tenor and express requirements of 35 U.S.C. 112, second paragraph, and are, thus, properly rejected.

Claims 12 and 42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

The recitation of the trademark MAGNASWEET MM-100 as a limitation of dependent claims 12 or 42 is a term that renders the scope of the claims indefinite. Applicant's attention is drawn to the MPEP at §2173.05(u), which states, "It is important to recognize that a trademark or trade name is used to

identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name...If the trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of the 35 U.S.C. 112, second paragraph...The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. In fact, the value of a trademark would be lost to the extent that it became descriptive of a product, rather than used as an identification of a source or origin of a product. Thus, the use of a trademark or trade name in a claim to identify or describe a material or product would not only render a claim indefinite, but would also constitute an improper use of the trademark or trade name."

For these reasons, the claims fail to meet the tenor and express requirements of 35 U.S.C. 112, second paragraph, and are, thus, properly rejected.

Claim 53 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Present claim 53 recites a composition consisting of the active pharmaceutical ingredients phenylephrine, pyrilamine and dextromethorphan tannate salts and excipients produced by a variety of process steps identified as (a)-(c), and additional step (d), which is directed to "combining excipients to said second solution, wherein said excipients are selected from the group consisting of preservatives...and hardness-increasing agents."

In particular, it is noted that the preamble of the claim does not clearly set forth whether the limitation of "tannate salts" that appears at line 3 of the claim is intended to solely modify the dextromethorphan component or whether it is also intended to modify the phenylephrine and pyrilamine components as well. In other words, the claim fails to clearly, precisely or deliberately set forth whether the composition consists of the tannate salts of each of the three components (i.e., phenylephrine,

pyrilamine and dextromethorphan) or whether it consists of phenylephrine, pyrilamine and the tannate salt of dextromethorphan.

For these reasons, the claim fails to meet the tenor and express requirements of 35 U.S.C. 112, second paragraph, and are, thus, properly rejected.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-21, 31-38, 40-48 and 53-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gordziel (U.S. Patent No. 6,287,597; 2001) in view of Venkataraman (U.S. Patent No. 6,509,492; 2003) and Chopdekar et al. (U.S. Patent No. 5,599,846; 1997), each already of record, and further in view of newly cited Singh et al. (U.S. Patent No. 5,759,579; 1998), for the reasons of record set forth at pages 12-17 of the previous Office Action dated October 30, 2006, of which said reasons are herein incorporated by reference.

Newly amended claims 1 and 53 now require the presence of a liquid pharmaceutical carrier (claim 1) or excipients (claim 53), comprised of preservatives, suspending agents, thickening agents, coloring agents, anti-caking agents, sweetening agents, flavoring agents, and pH adjusting agents, etc. Gordziel et al. teaches the use of magnesium aluminum silicate (i.e., anti-caking agent), methylparaben (i.e., preservative), coloring (e.g., red dye, Example 2), sucrose and saccharin sodium (i.e., sweetening agents), pectin (i.e., thickening agent), sodium hydroxide (i.e., pH adjusting agent) and natural and artificial flavors (e.g., strawberry flavor, Example 2) and part of the carrier used in the disclosed and exemplary suspension formulations. Please see Gordziel, col.2, l.53-col.3, l.20 (Example 2).

Though Gordziel does further include xanthan gum as a component of the suspension formulation, Singh et al. (U.S. Patent No. 5,759,579; 1998) is cited for its teachings of pharmaceutical suspension systems useful in, e.g., the formulation of antihistamines, decongestants, antitussives, etc., wherein the pharmaceutically acceptable liquid excipient suspending base for homogenously suspending solid pharmaceutically active compounds without excessive foam formation contains water, xanthan gum, and hydroxypropylmethylcellulose and eliminates the need for deaeration of the final batch, which provides more even doses of medication (i.e., by avoiding finely divided medicament trapped in the foam) and also reduces interactions between the suspension system and the active ingredients due to the non-ionic nature of the materials contained therein (i.e., xanthan gum and hydroxypropylmethylcellulose). Singh et al. further discloses an optimum pH of about 4-6.0 for the liquid suspensions, since this slightly acidic pH enhances preservation and stability of the composition. Please see Singh et al. at col.1, l.36-60 and col.2, l.27-43. Singh et al. provides exemplary suspension systems that further comprise sodium benzoate as a preservative (col.4, l.5-10) and artificial grape flavor (Example 3, col.6).

One of ordinary skill in the art at the time of the invention would have found it *prima facie* obvious to employ the slightly acidic suspension carrier of Singh et al. in combination with the suspension carrier of Gordziel and/or Venkataraman because said carrier of Singh et al. was known to

enhance the homogeneity of the final suspension and to also improve the stability of the final composition. Such a person would have been clearly motivated to do so by a desire to enhance the therapeutic effectiveness of the final composition by creating uniform dosage forms and also to stabilize the composition so as to increase shelf life and decrease degradation of the final composition.

Regarding the claimed wt% of the components of the liquid pharmaceutical carrier, the determination of the optimum wt% of the presently claimed carrier components would have been a matter well within the purview of one of ordinary skill in the art. Such a determination would have been made in accordance with a variety of factors, such as the amount of active ingredients to be administered, the palatability of the active ingredients, the ease of dissolution of such active ingredients, and the ease and speed at which the active ingredients degrade in the absence of adequate amounts of preservatives or stabilizers. Thus, the wt% that would have actually been employed would have varied widely and, in the absence of evidence to the contrary, the currently claimed specific wt% are not seen to be inconsistent with those that would have been determined by the skilled artisan.

Newly added claims 54-59 are properly included in the present rejection because such limitations further limit the process by which the product is made and fail to further limit the claimed product itself in any material, physical or structural nature.

Newly added claims 60-61 are also properly included in the present rejection because the cited references to Gordziel and Venkataraman in combination clearly teach a pharmaceutical composition in the form of a liquid suspension that consists essentially of pyrilamine tannate, phenylephrine tannate, dextromethorphan tannate and a liquid pharmaceutical carrier, which may further be comprised of various thickening agent, suspending agents, etc. as stated in claim 61. Please see the previous Office Action at pages 12-14.

Newly amended claim 31 now require the presence of excipients, comprised of diluents, dry binding/matrix forming agents, binding solutions, coloring agents, sweetening agents, hardness-increasing

agents and flavoring agents. Gordziel teaches the use of starch (understood to be corn starch), methylcellulose, dibasic calcium phosphate dihydrate powder, povidone, coloring and magnesium stearate as components of the disclosed tablet formulation. Please see Gordziel, col.2, l.23-50 and Example 1.

Though Gordziel does not specifically disclose the use of, e.g., lactose or microcrystalline cellulose, as components of the disclosed tablet formulation (see, e.g., present claim 36), Venkataraman teaches various carriers or excipients for oral administration that include, for example, corn starch, lactose, magnesium stearate, microcrystalline cellulose, povidone, etc., which are generally described as biologically inactive and can be administered to patients without causing deleterious interactions with the therapeutic agent(s) (col.5, l.66-col.6, l.12). One of ordinary skill in the art at the time of the invention would have found it *prima facie* obvious to incorporate any one or more of such ingredients as a pharmaceutically acceptable carrier or excipient in the oral tablet formulation of Gordziel in combination with Venkataraman to facilitate the manufacture and preparation of such a tablet. Such a person would have been motivated to use any one or more of such carriers and/or excipients in light of their biological inactivity and lack of biological interaction with the claimed therapeutic agents.

Furthermore, the use of various coloring agents, sweeteners or flavoring agents such as, e.g., those of present claims 41-43, would have naturally commended themselves to one of ordinary skill in the art at the time of the invention seeking to create a palatable and appealing pharmaceutical composition to facilitate administration and patient compliance with the prescribed regimen by masking unpleasant and bitter tastes and to formulate a product with an agreeable overall color.

Newly added claims 62-64 are also properly included in the present rejection because the cited references to Gordziel and Venkataraman in combination clearly teach a pharmaceutical composition in the form of a oral tablet that consists essentially of pyrilamine tannate, phenylephrine tannate, dextromethorphan tannate and a liquid pharmaceutical carrier, which may further be comprised of various

diluents, dry binding/matrix-forming agents, etc. as stated in claim 62. Please see the previous Office Action at pages 12-14. Furthermore, the determination of the claimed dosage amounts (claim 64) would have been a matter well within the purview of one of ordinary skill in the art, made in accordance with various factors, such as, but not limited to, the age, weight, sex, diet and medical condition of the patient, severity of the disease, the route of administration, pharmacological considerations, such as the activity, efficacy, pharmacokinetics and toxicology profiles of the particular compound employed, whether a drug delivery system is utilized and whether the compound is administered as part of a drug combination. Thus, the amounts that would have actually been employed would have varied widely and, in the absence of evidence to the contrary, the currently claimed specific amounts are not seen to be inconsistent with those that would have been determined by the skilled artisan.

In addition, the concentration of the active ingredients is a result-effective variable, i.e., a variable that achieves a recognized result, and, therefore, the determination of the optimum of workable dosage range would be well within the practice of routine experimentation by the skilled artisan, absent factual evidence to the contrary, and, further, absent any evidence demonstrating a patentable difference between the compositions used and the criticality of the amount(s).

Response to Applicant's Arguments

Applicant traverses the instant rejection, stating that Gordziel is only concerned with the combination of two sympathomimetic drugs, not the combination of sympathomimetic drugs and other non-sympathomimetic drugs, such as antitussive compounds, etc. Applicant asserts that the dextromethorphan compound of Applicant's invention is not a sympathomimetic compound and, therefore, there is no motivation to combine it with the sympathomimetic compounds of Gordziel. Applicant further alleges that Venkataraman discloses numerous combinations and fails to motivate the skilled artisan to choose the presently claimed compound to arrive at the presently clamed combination.

Applicant submits that while Applicant's combination may have been disclosed in the Venkataraman reference among numerous other possible combinations, there is no teaching, suggestion or motivation to the skilled artisan to choose the three compounds presently claimed. Applicant additionally asserts that the Chopdekar et al. reference fails to remedy the deficiencies of Gordziel or Venkataraman and does not teach, suggest or motivate any other combinations other than pyrilamine and phenylephrine.

Applicant's traversal has been fully and carefully considered in its entirety, but fails to be persuasive.

First, though Applicant alleges that the only motivation to make any combination of the composition disclosed by Gordziel with any other compound could only be based upon a similar mechanism of action (i.e., that the compound must be a sympathomimetic compound, just like the phenylephrine and pyrilamine compounds of Gordziel), Applicant is reminded that combinations of two compounds can be made for other valid reasons that flow logically from the teachings of the prior art that are not relevant to their mechanism of action. In the instant case, the present combination is clearly not made based on a common or shared mechanism of action, but rather based upon a common and shared therapeutic effect, i.e., that each is known for treating viral infections, cold symptoms, allergic rhinitis, runny nose, cough, post-nasal drip, rhinorrhea and sinusitis. These conditions are known to generally occur together as a result of, for example, the common cold virus, and, thus, the motivation to combine the three elements (i.e., phenylephrine tannate, pyrilamine tannate and the antitussive agent dextromethorphan tannate) flows logically from the fact that each components was known to be administered for a common therapeutic purpose and that the combination of all three agents would clearly result in a single composition with broader therapeutic effects and enhanced benefit to the patient.

Second, Applicant in some way believes that the comprehensiveness of the disclosure of Venkataraman teaches away from the fact that the reference explicitly teaches a combination of an antihistamine tannate compound, a decongestant tannate compound and an antitussive tannate compound,

of which the species of pyrilamine tannate (antihistamine), phenylephrine tannate (decongestant) and dextromethorphan tannate (antitussive) are expressly disclosed as exemplary species of each genus. Please see Table 1, col.7, l.52-col.8, l.15 and col.10, l.4-13. Applicant is reminded that the broader teachings of the references are not negated on the basis of the comprehensiveness of the teachings. Applicant's attention is directed to the MPEP at §2131.02 (see "A Reference That Clearly Names the Claimed Species Anticipates the Claim No Matter How Many Other Species Are Named"), which states, "A genus does not always anticipate a claim to a species within the genus. However, when the species is clearly named, the species claim is anticipated no matter how many other species are additionally named. *Ex parte A*, 17 USPQ2d 1716 (Bd. Pat. App. & Inter. 1990) (The claimed compound was named in a reference which also disclosed 45 other compounds. The Board held that the comprehensiveness of the listing did not negate the fact that the compound claimed was specifically taught. The Board compared the facts to the situation in which the compound was found in the Merck Index, saying that 'the tenth edition of the Merck Index lists ten thousand compounds. In our view, each and every one of those compounds is described' as that term is used in 35 U.S.C. 102(a), in that publication.'). Id. at 1718. See also *In re Simvaramakrishnan*, 673 F.2d 1383, 213 USPQ 441 (CCPA 1982)."

It is further noted that the present situation is not tantamount to picking and choosing at random from hundreds, thousands, or even possibly millions, of, for example, different combinations of compounds to arrive at a claimed combination that would not have been readily apparent to the skilled artisan. In fact, the instant case is extraordinarily less complicated: Venkataraman sets forth a limited number of classes of agents and a very limited set of tannate compounds within each class, of which Applicant's claimed compounds are specifically and expressly taught. Accordingly, the choice of using the claimed combination of agents has been readily placed within the skill of, and easily envisaged by, one of ordinary skill in the art.

Lastly, regarding Applicant's argument that Chopdekar et al. does not remedy the deficiencies of

the primary references, Applicant is reminded that Chopdekar et al. was cited solely for its teaching of methods of tannate salt production of various pharmaceutical ingredients, which was cited in Venkataraman as a method for producing homogenous tannate formulations of the disclosed therapeutic agents. Accordingly, reliance upon Chopdekar et al. was made in order to demonstrate that the art was well aware of methods of producing tannate salts that results in a high degree of homogeneity in the concentrations of the active pharmaceutical ingredients of the compositions produced by such a method and was not relied upon, nor asserted, to teach the claimed invention in its entirety.

For these reasons, and those previously made of record at pages 12-17 of the previous Office Action dated October 30, 2006, rejection of claims 1-21, 31-38, 40-48 and 53-64 remains proper and is **maintained**.

Double Patenting

Obviousness-Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-21, 31-38, 40-48 and 53-64 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-21 and 31-48 of copending U.S. Patent

Application No. 10/047,578, for the reasons of record set forth at pages 17-19 of the previous Office Action dated October 30, 2006, of which said reasons are herein incorporated by reference.

Cancellation of copending claim 53 renders the instant rejection **moot** over such a claim.

Newly amended claims 1 and 31 now require the presence of, respectively, a liquid pharmaceutical carrier or an excipient in the claimed dosage forms. The copending claims clearly provide for the use of various dispersing agents, thickening agents, sweeteners, flavoring agents, preservatives, pH adjusting agents, coloring agents, dry binding/matrix forming agents, etc. as components of the disclosed copending formulations. Accordingly, the use of such carriers, diluents and/or excipients in varying amounts would have naturally commended itself, and would have been *prima facie* obvious to, one of ordinary skill in the art at the time of the invention. Such a person would have been motivated to do so in order to create palatable, appealing and stable dosage forms that are capable of resisting degradation and also to facilitate the formulation of the claimed active ingredients into the claimed dosage forms. The optimum amounts of such agents would have been reasonably expected to vary widely depending on the dosage form to be manufactured, the amounts of the claimed active principles and the palatability of the active principles themselves and are, therefore, not amounts that would have been inconsistent with those that would have been determined by one of ordinary skill in the art at the time of the invention.

Newly added claims 54-59 are properly included in the present rejection because claims 54-59 are directed to limitations of the process by which the presently claimed product is produced and do not impart a material or physical limitation of the structure or content of the product. Accordingly, such limitations are not considered to be a patentable distinction of the claimed product over the copending product since the overall structure and physical components of the present claims are rendered obvious by the copending claims.

Furthermore, newly added claims 60-64 are also properly included in the present rejection because the copending claims clearly provide for compositions consisting essentially of the tannate salts

of pyrilamine and phenylephrine, further in combination with various carrier materials (i.e., dispersing agents, thickening agents, sweeteners, flavoring agents, preservatives, pH adjusting agents, coloring agents, dry binding/matrix forming agents). Though the copending claims do not expressly provide for the inclusion of the dextromethorphan tannate component, Venkataraman is cited (U.S. Patent No. 6,509,492; 2003) for its teachings of various combination products of antihistamines, nasal decongestants, brochodilators, cough suppressants, antitussives and/or expectorants for the treatment of cough, cold, allergic rhinitis, etc. (col.2, l.19-37), of which pyrilamine tannate is identified as an antihistamine and phenylephrine tannate is identified as a decongestant (Table 1, col.7-8). Venkataraman further teaches the administration of dextromethorphan tannate as an antitussive agent effective to provide temporary relief from coughs due to cold, allergic rhinitis, etc. (col.7, l.58-67). One of ordinary skill in the art would have found it *prima facie* obvious to include dextromethorphan tannate as a component of the copending composition because each was known for the same therapeutic purpose for treating the symptoms resulting from colds, allergic rhinitis, etc. The very fact that each was known in the prior art to have the same therapeutic utility raises the reasonable expectation of success that the two compositions, when combined, would have, at minimum, additive, if not synergistic, rheumatoid arthritis-ameliorating effects when combined.

As stated in *In re Kerkhoven*, 626 F.2d 846, 205 USPQ 1069, at page 1072 (CCPA 1980): "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose. *In re Susi*, 58 CCPA 1074, 1079-80, 440 F.2d 442, 445, 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21, 279 F.2d 274, 276-77, 126 USPQ 186, 188 (CCPA 1960)."

It is noted that the skilled artisan would have been further motivated to combine dextromethorphan tannate with the copending composition to provide a single composition with broader therapeutic effects and an enhanced benefit to the patient being treated.

Applicant states that consideration of filing a Terminal Disclaimer will be made when the obviousness-type double patenting rejection is the only rejection that remains and, further, if the claims are actually an obvious variation of the copending claims.

In view of the fact that the present rejection is not the sole rejection that remains in the instant case, the rejection remains proper and is hereby **maintained**.

For these reasons stated *supra*, and those previously made of record at pages 17-19 of the Office Action dated October 30, 2006, rejection of claims 1-21, 31-38, 40-48 and 53-64 remains proper and is **maintained**.

Conclusion

Rejection of claims 1-21, 31-38, 40-48 and 53-64 remains proper and is **maintained**.

No claims of the present application are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Leslie A. Goyds
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May 21, 2007

Ardin H. Marschel 5/27/07
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER